

**Notice of Allowability**

Application No.

10/522,227

Applicant(s)

BONJOUKLIAN ET AL.

Examiner

Janet L. Coppins

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' Amendment of August 21, 2007.
2. ☒ The allowed claim(s) is/are 1,2,4,17 and 24-28.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

### **DETAILED ACTION**

1. Claims 1, 2, 4, 17 and 24-28 are currently pending in the instant application.

#### ***Response to Amendment***

2. Receipt is acknowledged of Applicants' Amendment and Response of August 21, 2007, which has been entered in the file. Accordingly, the amendments to the Specification have been entered, claims 18, 19, 21 and 23 have been cancelled, claim 1 has been amended, and new claim 28 has been added.

#### ***Claim Rejections - 35 USC § 103***

3. Claim 1 previously rejected under 35 U.S.C. 103(a) as being unpatentable over Kai et al. Claims 1 and 17 previously rejected under 35 U.S.C. 103(a) as being unpatentable over Gaster et al. In view of Applicants' persuasive arguments and amendments to the claims, the Examiner withdraws the obviousness rejections to the claims.

#### ***Double Patenting***

4. Claims 1, 2 and 17 provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-3 and 5 of copending Appl. No. 10/597,359. In view of Applicants' persuasive arguments and amendatory changes, the Examiner withdraws the rejections to the claims.

#### ***Allowable Subject Matter***

5. Claims 1, 2, 4 and 17 now appear allowable over the prior art. Accordingly, claim 28, drawn to a method of using the allowable compounds, is herein rejoined for examination on the merits.

### **REASONS FOR ALLOWANCE**

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6. In view of Applicant's amendatory changes and cancellations, claims 1, 2, 4, 17 and 24-28 are allowable over the prior art, as newly renumbered claims 1-9. The following is an examiner's statement of reasons for allowance:

This invention relates to novel benzimidazole or benzothiazole derivatives, their pharmaceutical compositions, and their methods of use. The allowable compounds are limited to compounds according to Formula I of claim 1, that are useful as p38 kinase inhibitors. Certain benzimidazole compounds are known in the art as having the ability to inhibit the activity of p38 kinase, however the aspect of preparing the instant claimed benzimidazole or benzothiazole derivatives, with anti-tumor activity, is novel and unobvious. Applicants demonstrate the ability of the instant compounds to selectively inhibit p38 MAPK in tumors (please refer to the *in vivo* inhibitory results, discussed on pages 109-112 of the specification), which makes them useful as anti-inflammatory and anti-tumor agents. After a thorough search, the closest of prior art, Wang, et al, J. Med. Chem, was found to teach similar heteroaryl compounds with cytotoxic activity. However the journal article fails to teach or render obvious the same instant claimed compounds according to Formula I, and does not fairly suggest methods of using the instant claimed compounds as p38 MAPK inhibitors for lung melanoma metastasis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Telephone Inquiry***

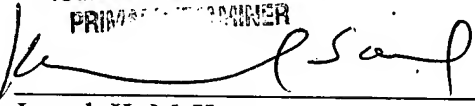
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins  
Patent Examiner, Art Unit 1626

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PRIMARY EXAMINER  
  
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September 30, 2007